K092363

510(K) SUMMARY

Submission Date: August 4, 2009

MAR 18 2010

Submitter Information:

Company Name: Riverain Medical Group, LLC.

Company Address: 3020 South Tech Blvd., Miamisburg, OH 45342-4860

Contact Person: Jennifer Vetter
Director, Regulatory Affairs and Quality Assurance
Riverain Medical
800.990.3387
937.425.6493
jvetter@riverainmedical.com

Device Information:

Trade Name: SoftView™

Regulation Number: 21 CFR §892.2050

Regulation Name: System, Image Processing, Radiological

Regulatory Class: Class II

Product Code: LLZ

Predicate Device:
Dual Energy and Tissue Equalization Software Options (K013481)
GE Medical Systems
Class II

Device Description: SoftView is a dedicated post-processing application which suppresses bone structures from digital radiographic images of the chest.

Intended Use: SoftView is intended to generate a bone-suppressed image from a original PA/AP chest radiograph.

Indications for Use: **SoftView** is intended to generate an enhanced, secondary digital radiographic image of the chest. The enhanced AP or PA image of the chest provides improved visibility of the lung parenchyma through bone suppression and tissue

equalization, and may facilitate discerning the presence or absence of nodules. The SoftView image provides adjunctive information and is not a substitute for the original PA/AP image. This device is intended to be used by trained professionals, such as physicians, radiologists, and technicians on patients with risk of having lung nodules and is not intended to be used on pediatric patients.

Comparison to Predicate Device:

SoftView is substantially equivalent to the cited predicate device. Differences in the design and performance from the cited predicate device do not affect either the safety or effectiveness of SoftView for its intended use.

Conclusion:

SoftView is a mathematical model of a DES system that operates on a standard chest X-ray. It is an accurate representation of the soft tissue image produced by the predicate device's hardware/software process. The model is built from DES data by using simple image features extracted from the standard PA, along with target values derived from a DES soft tissue image. Thus, although SoftView does not generate the soft tissue image based on two exposures to the patient in real time, it is an accurate mathematical model of the process. The result of SoftView processing is a soft tissue image of the patient, consistent with that produced by a DES device but without requiring any additional radiation dose to the patient. Effectiveness of this model was demonstrated both by a reader study and by a comparative analysis of the contrast-to-noise ratio (CNR) of the residual bone in the predicate device's images in the soft tissue rib and clavicle regions, relative to the subject device.

Reader Study Results:

A reader study was conducted to assess the benefit of SoftView to a radiologist for detecting actionable lung nodules. Reader performance was quantified by the area under the Localization Receiver-Operating Characteristic (LROC), curve which measures the conjoint ability to detect and correctly localize a true positive location on the radiograph. The difference in the average area under the LROC curve with and without the aid of SoftView was used to assess performance. The mean difference in the area under the curves was -0.098 (95% CI: -0.116 to -0.080), a statistically significant improvement. Sensitivity was 49.5% (95% CI:

45.9-53.0) without SoftView and 66.3% (95% CI: 63.1-69.7) with the addition of the SoftView image. Specificity was 96.1% (95% CI: 95.0-97.1) with the standard image and 91.8% (95% CI: 89.5-93.5) with the SoftView image.

Substantial Equivalence: To establish substantial equivalence, a comparative analysis of the contrast-to-noise ratio (CNR) of the residual bone in the predicate device's soft tissue images versus the subject device was performed. A CNR analysis was performed for both the GE and Fuji dual energy subtraction (DES) soft tissue images.

Analysis of scatter plots of the contrast-to-noise ratio (CNR) for the residual rib objects for an independent dataset was used to compare the SoftView correlative relationship relative to DES. Statistical hypothesis tests were also performed on the independent dataset. Two series of tests were performed, equivalency and non-inferiority tests. Data were stratified across modality, CR (Fuji DES), DR (GE DES), and lung regions, i.e., pleural, mid-lung, and hilum.

For the indicated strata of the data, it was demonstrated that SoftView is equivalent to the DES soft tissue images. The exception was the middle area of the lung for the DR modality (GE DES). SoftView was found to be better in this region based on an "ideal" CNR of the residual ribs in the soft tissue image being 0.0. Furthermore, a non-inferiority test demonstrated that SoftView was non-inferior to the DR and CR dual energy devices soft tissue images across all strata. Descriptive statistics of the means and standard deviations of the CNRs across the different modalities and regions of the lungs were in agreement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAR 18 2010

Ms. Jennifer Vetter
Director-Regulatory and Quality Assurance
Riverain Medical Group, LLC
3020 South Tech Blvd.
MIAMISBURG OH 45342

Re: K092363
Trade/Device Name: Softview™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 5, 2010
Received: February 12, 2010

Dear Ms. Vetter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

2.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K_____

Device Name: SoftView™

Indications for Use:

SoftView is intended to generate an enhanced, secondary digital radiographic image of the chest. The enhanced AP or PA image of the chest provides improved visibility of the lung parenchyma through bone suppression and tissue equalization, and may facilitate discerning the presence or absence of nodules. The SoftView image provides adjunctive information and is not a substitute for the original PA/AP image. This device is intended to be used by trained professionals, such as physicians, radiologists, and technicians on patients with risk of having lung nodules and is not intended to be used on pediatric patients.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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